

Application No. 10/616887  
Amendment dated November 20, 2006  
After Final Office Action of May 22, 2006

Docket No.: 023372.0110CIUS

### REMARKS

In view of the above amendment and below remarks, applicants believe the pending application is in condition for allowance.

Applicants have amended claim 11 and added two dependent claims, 45 and 46. No new matter has been added.

The Applicants' representative thanks the Examiner for the courtesies extended during the personal interview, the substance of which is incorporated into the following remarks.

The Examiner has rejected claims 11-13, 20, 28-30 and 37-40 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,503,247 (Swartz et al.).

The Examiner states that Swartz discloses a vascular medical device (10; see figure 6) comprising a main shaft (12) with an anchor balloon (20), peripheral balloon (22), pair of electrodes (30; sensing electrodes col. 15:9-14), RF power source (col. 11:49-50), and a temperature feedback control (col. 12:60-62); and contends that the double-balloon electrode catheter structure of Swartz would be capable of blood delimiting (through disclosed seals) as claimed by the Applicant. Applicants respectfully disagree.

Swartz discloses a process and device for the treatment of atrial arrhythmia, in particular, using ablation procedures. The device shown in Figs. 3-10 includes a catheter with seals 20, 22. The seals are secured at different locations on the catheter forming a space between them and an ablating system for ablating tissue is located between the seals. (See, e.g., Swartz at col. 9, lines 34-40.) The catheter and seals are positioned within the pulmonary vein. (See Fig. 2; col. 14, line 33 - col. 15, line 14.) Seal 20 is the distal balloon and must completely stop the flow of blood into the space between seals 20,22. (col. 10 at lines 15-27.) Proximal balloon 22 seals off any backflow of blood and must substantially occlude the pulmonary vein. (col. 10, lines 29-65.) Chemical ablating material is introduced into the space between the two seals 20, 22 through openings 28 in the catheter. (col. 12, lines 14-27.) Also secured between the seals 20, 22 is an ablating system, which is a radiofrequency ring electrode 30 secured to the catheter

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operating in conjunction with the conductive media that has been introduced between the two seals. (Col. 12, lines 46-59.) The Rf electrode 30 emits energy which is conducted by the conductive media to the tissue in the vein between the seals 20, 22 to create a circumferential lesion of sufficient width and breadth to block the passage of atrial premature contractions. (Col. 14, line 66 - col. 15, line 14.) The space between seals 20, 22 can be adjusted to control the size of the lesion formed during the ablation procedures. (Col. 13, lines 14-24.)

In stark contrast, all the claims of this application call for a "hemostasis" device. As discussed during the interview, a hemostasis device is for closing a puncture in the artery wall. A hemostasis device for closing a puncture in a wall of an artery is completely different from a catheter positioned within a vein to ablate the tissue and occlude inside the vein. Independent claims 11, 28 and 38 all claim a hemostasis device for closure of a puncture. Swartz fails to disclose, explicitly or inherently, at least this feature of the independent claims. The rejection should be withdrawn at least for failing to meet this feature of the claims.

The office action points out that the "[n]ew art presented (Swartz et al.) is directed toward a method unrelated to hemostasis, however the rejection above indicated that through structural equivalence would be capable of the hemostasis related functions disclosed in the Applicant's claimed device." (Office Action at page 4.) Applicants' respectfully disagree. In taking this position, the office action disregards literal language in the claims. Independent claims 11, 28 and 38 specify a type of structure that causes hemostasis and closure of the puncture. Nowhere does Swartz disclose, literally or inherently, this language appearing in claims 11, 28 and 38. In fact, Swartz teaches structural non-equivalence. Swartz teaches that the function of its device is for ablating veins by inserting the catheter into the vein, expanding both seals inside the vessel and causing a circumferential lesion to block the passage of the vein. Swartz is not equivalent to the claimed invention, which is healing or restoring a vessel by closing a puncture in the wall of the vasculature and allowing the vein to continue functioning in its normal manner with blood flow there through. Withdrawal of this basis for the rejection is respectfully requested.

Furthermore, claim 11 has been amended and claims 45 and 46 have been added to specify that the electrode "is disposed at a distal tip of the main shaft", operable to supply an electric current and to thereby heat the volume of blood adjacent to the electrode and to cause

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coagulation of the blood and closure of the puncture. According to the office action at page 3, Swartz discloses "electrodes (30 sensing electrodes col. 15:9-14)". But, the Swartz electrodes relied upon by the examiner are between the Swartz seals 20, 22 so that a blocking lesion can be formed in the vein; they are not at the distal tip as claimed in claims 11, 45 and 46 and do not, explicitly or inherently, function to close a puncture. (It is noted that the office action was correct in not relying on the electrode 25 in Swartz because electrode 25 is utilized to monitor the electrical activity within the pulmonary vein and to map the location with pulmonary vein, for example, at col. 10, lines 14, and cannot explicitly, inherently or otherwise meet the features of these claims.) Accordingly, claims 11, 45 and 46 are allowable for these additional features recited therein.

In the Office Action, dependent claims 14-19, 31-36 and 41-44 under have been rejected 35 U.S.C. 103(a) as being unpatentable over Swartz in view of U.S. Patent No. 4,211,230 (Woltosz). The rejection is respectfully traversed at least for the reasons discussed above with respect to the respective independent claims and for the additional features recited in the respective dependent claims. Withdrawal of the rejection is respectfully requested.

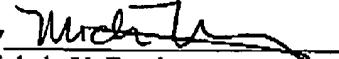
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Applicant has included proper fees for this response. If any additional fees are due, please charge our Deposit Account No. 50-2228, under Order No. 023372.0110C1US from which the undersigned is authorized to draw.

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Respectfully submitted,

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